Section E: 510(K) Summary

K013881

Applicant:

Ribbond, Inc.
1420 3rd AVE STE 1030
Seattle, WA 98101
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JAN 2 5 2002

Contact person: Shoshana Rudo Driver

Date prepared: October 22, 2001

Device Trade Name: Ribbond-Triaxial

Device Common Name: Fiber reinforcement material

Device Classification Name: Denture realigning, repairing or rebasing resin (CFR 872.3760)

Description of Device:
Ribbond-Triaxial is a fiber reinforcement used to reinforce dental resins. It is made of ultra-high-molecular-weight polyethylene (UHMW). The fibers are braided using a triaxial braid and subjected to a plasma treatment to improve its ability to bond to resins.

Intended Use:
Ribbond-Triaxial is intended to provide reinforcement to acrylic or composite resins used for dental restorations. It can be used for the following applications:

As reinforcement in manufacturing and/or repairing full or partial-dentures as well as overdentures, night-guards and orthodontic appliances.

To repair and reinforce resin or composite prostheses including temporary and permanent bonded and removable bridges.

To reinforce splints used to immobilize teeth.

Substantial Equivalency:
Ribbond-Triaxial is substantially equivalent to Ribbond, cleared under K913040 dated October 7, 1991.

Description of new design characteristics
Ribbond-Triaxial is made using a triaxial braid. Ribbond is made using a leno-weave. Tests show that Ribbond-Triaxial has greater load carrying capacity than the leno-weave. The different design characteristics of Ribbond-Triaxial does not raise new questions of safety and effectiveness and demonstrates that the device is as safe and effective as the predicate device.

Ribbond-Triaxial is made of the UHMW fiber and treated with plasma the same manner as the predicate device. Therefor there are no new hazards presented with Ribbond-Triaxial as with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Ms. Shoshanna Rudo Driver
Vice President
Ribbond, Incorporated
1402 3rd Avenue, Suite 1030
Seattle, Washington 98101

Re: K013881
Trade/Device Name: Ribbond-Triaxial®
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: November 19, 2001
Received: November 23, 2001

Dear Ms. Driver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D Statement of indications for use

Intended Use:

Ribbond-Triaxial is intended to provide reinforcement to acrylic or composite resins used for dental restorations. It is used by dentists and dental technicians. It can be used for the following applications:

As reinforcement in manufacturing and/or repairing full or partial-dentures as well as overdentures, night-guards and orthodontic appliances.

To repair and reinforce resin or composite prostheses including temporary and permanent bonded and removable bridges.

To reinforce splints used to immobilize teeth.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013881